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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,425	07/31/2001	Bruce B. Lee	M-11515 US	5907

24251 7590 09/13/2002

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EXAMINER
VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 09/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,425	LEE, BRUCE B.	
	Examiner	Art Unit	
	Peter J Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7-31-01* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites non-statutory subject matter making the scope of the invention unclear.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 27 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The applicant is positively reciting the surgeon and the patient in relation to the location of the monitor in lines 9-11. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-

> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1,2,7, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Savage et al. ('453).

Re: independent claim 1 and dependent claims 7,9,20,22, Savage et al. (Savage) discloses especially in figure 3 a method and system (40) for treating a pelvic tumor (can be in the uterus; column 2 line 33) comprising insertion into a pelvic region (shaded), positioning the ablation device (30) proximate the pelvic tumor (T), confirming the placement of the ablation device with a laparoscope (column 5 lines 33-36) and an ultrasound imaging device including a monitor (46; column 5 lines 43-49), and delivery of RF energy by electrode coupled to a RF energy source (42) through the ablation device (column 5 lines 38-43) to ablate the tumor.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-4 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savage in view of Burbank et al. ('601).

Savage, which has been described above, neglects to *explicitly* disclose insertion of the device through the cervix or abdomen.

Burbank discloses a uterine tumor ablation protocol in which the ablation device is inserted transvaginally (through the cervix), as well as retroperitoneally (through the abdomen) Note abstract.

Therefore, it would have been obvious to one of ordinary skill in the art to modify Savage in view of Burbank by accessing the uterus by traversing the cervix in order to provide a minimally invasive route to the tumor and by traversing the abdomen to provide an alternate route.

Claims 5-6,8, and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savage in view of Behl ('433).

Re: claim 8, Savage discloses ultrasound imaging (46,32; column 5 lines 43-45) of the tumor in figure 3. Element 48 represents the image plane. From this illustration and through routine experimentation, one could determine optimal placement of the incision through which the ultrasound device is received (top, bottom, etc.)

Savage, which has been described above, neglects to disclose insertion of the ablation device directly into the tumor and a plurality of deployable arms.

Behl discloses a tumor ablation device (20; fig. 2) that is inserted into a tumor (T) as illustrated in figure 6c. Moreover, Behl discloses a plurality of deployable electrode arms (32; figures 3 & 6c; column 10 lines 21-24.)

Therefore, it would have been obvious to one of ordinary skill in the art to modify Savage in view of Behl by including a plurality of deployable electrode arms as a design expedient in order to uniformly generate heat throughout a desired target tissue volume through the use of symmetrically spaced apart electrodes as disclosed in Behl column 1 lines 36-39.

Claims 10-13,16,20-23, and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savage.

Re: independent claims 12, 27 and claim 13, taken in combination with remarks above regarding independent claim 1 a 35 USC § 103 rejection is appropriate as optimal (assuming the applicant's assertions are optimal) placement of the monitor, the energy source, imaging device, and the patient in the operating room could be determined through routine experimentation or harmless trial and error. Further, the examiner contends that the disclosed placement is obvious to any surgeon that normally deals with similar equipment during similar surgeries and that the specification is silent regarding statements of criticality or unexpected results that could arise from the disclosed placement.

Re: claim 16, repositioning the uterus relative to the ablation device, as a method step would be determined through harmless trial and error by the average surgeon upon performing the surgery if conditions called for it.

Re: claim 25, it would also have been obvious that if more than one tumor was present, both would be treated sequentially.

Re: claims 10,11,23, and 30, through routine experimentation the optimal tumor size, ablation temperatures and time of application could be determined.

Several of the applicant's claims include steps that have been deemed obvious. The applicant to appropriately address these rejections should provide arguments that posit statements of criticality. In other words, how are the steps essential to the efficacy of the surgery and why would those steps not be obvious or easily determined through routine experimentation or harmless trial and error.

Therefore, it would have been obvious from Savage through routine experimentation parameters of tumor size, ablation temperature, time of application, incision placement, and operating room configuration in order to provide a most efficacious uterine tumor ablation protocol.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Savage in view of Burbank and further in view of Schmaltz et al ('383).

Savage and Burbank, which have been described above, neglect to disclose rotation of the device during insertion.

Schmaltz et al. (Schmaltz) discloses a rotatable electrode device (10) for treatment of uterine tumors. The device rotates to facilitate entry and passage through tissue such as abdominal. Note column 3 lines 3-5.

Therefore, it would have been obvious to one of ordinary skill in the art to modify Savage in view of Burbank and further in view of Schmaltz by including a rotatable ablation device in order to facilitate entry and passage through tissue as disclosed by Schmaltz column 3 lines 3-5.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Savage in view of Moorman et al. ('033).

Savage, which has been described above, neglects to disclose cauterizing the withdrawal track of the ablation device. Note column 12 lines 16-21.

Moorman et al. discloses cauterizing the withdrawal track of the ablation device.

Therefore, it would have been obvious to one of ordinary skill in the art to modify Savage in view of Moorman et al. by cauterizing the withdrawal track of the ablation device in order to reduce bleeding and to kill any displaced tumor cells.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers

for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700

Pete Vrettakos
September 3, 2002